

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 12-444V

Filed: July 2, 2014

(To be published)

RONALD KEATON

Petitioner,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

*

*

*

*

*

*

*

*

*

Proof of Vaccination; Fact Ruling and
Dismissal Decision; Flu Vaccine;
GBS; CIDP; Ruling on the Record

Firooz Namei, Esq., McKinney & Namei Company, L.P.A., Cincinnati, Ohio, for Petitioner.
Debra Begley, Esq., U.S. Department of Justice, Washington, DC, for Respondent.

FACT RULING AND DISMISSAL DECISION¹

Gowen, Special Master:

On July 17, 2012, petitioner, Ronald Keaton, filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, et seq. (“the Act”). The petition alleged that the seasonal influenza vaccine and pneumonia vaccine² petitioner received

¹ Because this published decision contains a reasoned explanation for the action in this case, I intend to post this decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, § 205, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). In accordance with Vaccine Rule 18(b), petitioners have 14 days to identify and move to delete medical or other information, that satisfies the criteria in § 300aa-12(d)(4)(B). Further, consistent with the rule requirement, a motion for redaction must include a proposed redacted decision. If, upon review, I agree that the identified material fits within the requirements of that provision, I will delete such material from public access.

² The adult pneumococcal vaccine, which was administered on August 31, 2010, is not a vaccine covered by the Vaccine Act. See 42 C.F.R. § 100.3. With some exceptions for certain risk factors, children are administered a pneumococcal conjugate vaccine (Prevnar) while adults receive pneumococcal polysaccharide vaccines (Pneumovax). See <http://www.cdc.gov/vaccines/vpd-vac/pneumo/default.htm> (last visited 5/28/2014). Although the childhood formulation of the pneumococcal vaccine appears on the Vaccine Injury Table, the adult formulation does not. 42 C.F.R. § 100.3; see also *Schmidt v. Sec'y, HHS*, No. 11-410V, 2011 WL 6148590, at *2 (Fed. Cl. Spec. Mstr. Nov. 21, 2011); *Morrison v. Sec'y, HHS*, No. 04-1683V, 2005 WL 2008245, at *2 (Fed. Cl. Spec. Mstr. July 26, 2005); *Finley v. Sec'y, HHS*, No. 04-874V, 2004 WL 2059490, at *2 (Fed. Cl. Spec. Mstr. Aug. 24, 2004) (finding that pneumococcal polysaccharide vaccines are not covered under the Vaccine Program).

on August 31, 2010, caused his chronic inflammatory demyelinating polyneuropathy [CIPD]. Further, petitioner states in his petition that initially he was diagnosed with Miller-Fisher variant acute inflammatory demyelinating poly-neuropathy [AIDP], often referred to as Guillain-Barre syndrome [GBS] and the condition evolved to CIDP.

This case was initially assigned to Special Master Daria Zane on July 17, 2012, subsequently to Chief Special Master Denise Vowell on September 23, 2013, and finally to Special Master Thomas L. Gowen on March 5, 2014.

The adult pneumococcal vaccine is not a vaccine covered under the Act and thus, petitioner's claim is limited to a claim for injury due to the influenza vaccine. Respondent has raised the issue of whether petitioner actually received a covered vaccine as pled in the petition, based on her belief that petitioner had not filed sufficient evidence to support a finding that he received an influenza vaccine on August 31, 2010. A hearing was held, interrogatories answered, additional medical records filed and a status conference held on February 27, 2014, during which the parties requested a ruling on the record. After consideration of the record, I have concluded that petitioner has been unable to show by a preponderance of the evidence that a flu vaccine was administered on August 31, 2010³ and thus this claim must be dismissed.

I. Standards for Finding Vaccination

A petitioner must prove as a threshold matter that he received a vaccine covered by the Act within the United States, with certain exceptions not relevant to the instant action. 42 U.S.C. § 300aa-11(C)(1)(A) and (B). In determining the persuasiveness of the evidence, the special master must assess "the record as a whole" and may not find that a petitioner received a vaccine "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." 42 U.S.C. § 300aa-13(a)(1). Vaccine Rule 2 requires, in accordance with 42 U.S.C. § 300aa-11(c), that a petition shall be accompanied by "all available medical records supporting the allegations in the petition, including physician and hospital records relating to: the vaccination itself." Vaccine Rule 2(c)(2)(A)(i).

Although contemporaneous documentation of vaccination from a health care provider is the best evidence, its production is not an absolute requirement. See Centmehaiey v. Sec'y, HHS, 32 Fed. Cl. 612, 621 (1995) ("The lack of contemporaneous documentary proof of a vaccination . . . does not necessarily bar recovery."). Vaccine Rule 2 states that "[i]f the required medical records are not submitted, the petitioner must include an affidavit detailing the efforts made to obtain such records and the reasons for their unavailability." Vaccine Rule 2(c)(2)(B)(i). Furthermore, if petitioner's claim is "based in any part on the observations or testimony of any person, the petitioner should include the substance of each person's proposed testimony in a detailed affidavit(s) supporting all elements of the allegations made in the petition." Vaccine Rule 2(c)(2)(B)(ii).

³ Additionally, as discussed in the procedural history, petitioner alleged that an additional flu vaccine was administered on January 28, 2011. However, the record from the time of the alleged additional flu vaccine, specifically the Riverside Methodist Pharmacy record, filed on February 1, 2014, does not support petitioner's claim. See Pet. Ex. 19.

Special masters have found in favor of vaccine administration where direct documentation of vaccination is unavailable. In such cases, preponderant evidence was found in other medical records and/or witness testimony. For example, corroborative, though backward-looking, medical notations have been found to tip the evidentiary scale in favor of vaccine receipt. See Lamberti v. Sec’y, HHS, No. 99-507V, 2007 WL 1772058, at *7 (Fed. Cl. Spec. Mstr. May 31, 2007) (finding multiple medical record references to vaccine receipt constituted adequate evidence of administration); Groht v. Sec’y, HHS, No. 00-287V, 2006 WL 3342222, at *2 (Fed. Cl. Spec. Mstr. Oct. 30, 2006).

In addition to corroborative medical records, witness testimony has been found to be a sufficient basis for finding that a vaccine was administered as alleged. Alger v. Sec’y, HHS, No. 89-31V, 1990 WL 293408, at *2, 7 (Fed. Cl. Spec. Mstr. Mar. 14, 1990) (finding oral testimony from a parent and the doctor who administered the vaccine to be “more than adequate to support a finding that the vaccine was administered.”).

II. Procedural History

The petition filed on July 17, 2012, alleges that petitioner suffered from CIDP as a result of receiving the flu vaccination. Petition at 1. Petitioner contends he received the flu vaccine, on August 31, 2010, at the Central Ohio Pulmonary Disease and Sleep Medicine, Inc. “COPD” practice in Westerville, Ohio. Id. at 3. Initially, petitioner filed eight medical record exhibits and petitioner’s affidavit, between September 25, 2012, and December 20, 2012. Petitioner’s Exhibits [hereinafter “Pet. Ex(s).”] at 1-9.⁴ Medical records from the COPD practice did not contain a record of the flu vaccination. See Pet. Exs. 1, 3C. On January 9, 2013, petitioner filed a note from the COPD practice administrator and an insurance form. Pet. Ex. 10 (indicating that petitioner received a flu vaccine on Aug. 31, 2010); Pet. Ex. 11.

Respondent, in her January 14, 2013 status report, indicated that she did not believe the evidence filed to date was sufficient to establish by preponderant evidence that petitioner received a covered vaccine. Respondent’s Status Report, filed Jan. 14, 2013. Specifically, respondent questioned that, while the note from the COPD practice administrator indicated that petitioner received a flu vaccine, the note “failed to explain what records the administrator reviewed/relied on for her assertion.” Id. at 2. Petitioner continued to submit additional medical records, another affidavit, and a letter from his wife and her journal, to support his allegations. Pet. Exs. 3C, 12-16. In order to address the concerns raised, Special Master Zane and the parties agreed to hold a fact hearing on the issue of “whether petitioner actually received an influenza vaccination at [COPD], on or about August 31, 2010.” Hearing Order, May 30, 2013.

At that hearing, Mr. and Mrs. Keaton testified that Mr. Keaton had received a flu shot on August 31, 2010. Transcript [hereinafter “Tr.”] at 12, 78, 82-83. Although several questions

⁴ Petitioner’s Exhibit 3 was initially filed on September 25, 2012, but was struck from the docket as incomplete on April 11, 2013, because several pages of the exhibit were missing. Motion to Strike, filed Apr. 11, 2013. A complete Petitioner’s Exhibit 3, containing the missing pages, was refiled later that day. Order, filed Apr. 11, 2013. On May 7, 2013, the complete Petitioner’s Exhibit 3 was superseded by a re-paginated version, entitled Petitioner’s “Exhibit 3C.” Order, filed May, 7 2013 (Petitioner’s Exhibit 13, initially filed on April 11, 2013, was also superseded by a re-paginated version, entitled Petitioner’s “Exhibit 13C”).

were asked and answered addressing the date of symptom onset, any reference to symptom onset in this opinion is for purposes of context only and is not essential to the decision, which is limited to the issue of whether petitioner has proven by a preponderance of the evidence that he received the flu vaccine. Id.

Finally, after the hearing, petitioner filed additional medical records and the parties agreed to interrogatories which were submitted to the COPD practice in Westerville, Ohio, where Mr. Keaton indicated that he had received the flu shot. Pet. Exs. 17-18; Order, filed July 16, 2013. Verified answers to the interrogatories were prepared by Sheri Whalen, the practice administrator of the COPD practice, and filed into the record by an order issued by Special Master Zane. See Order: Filing Responses from Third Party in Record, Appendix B, Interrogatory Answers, filed Aug. 30, 2013 [hereinafter “Interrog(s). 1-39”].

During a status conference held on October 23, 2013, petitioner requested the opportunity to pursue medical records reflecting his receipt of an additional influenza vaccine on January 28, 2011, during his hospitalization. Order, filed Oct. 24, 2013. The parties also agreed, during the status conference, that pending petitioner’s efforts to obtain additional medical records, the case was positioned for a ruling on the record. Id.

On February 1, 2014, petitioner filed Petitioner’s Exhibit 19, the record from the Pharmacy Department of Riverside Methodist Hospital. Pet. Ex. 19. After review of the pharmacy records, I determined that those records do not support petitioner’s claim that he received a flu vaccine on January 28, 2011.

A status conference was held on February 27, 2014, to discuss petitioner’s pharmacy records and determine any next steps in this matter. During the status conference, petitioner’s counsel acknowledged that he is unable to prove petitioner received a flu vaccine on January 28, 2011, based on the record filed. Order, filed Feb. 27, 2014. Further, the parties requested a ruling on the record and petitioner confirmed that the record was complete. Id. The parties were informed that they were welcome, although not required, to file any additional matters or arguments in the absence of an order to do so. Id. To date, no additional filings have been made.

Thus, this case is ripe for a ruling on the record.

III. Factual History

Petitioner, born in 1954, is a veteran of the United States Army, and has worked as a truck driver since the 1970s. Tr. at 53-54. He contends that he received a flu shot and a pneumonia vaccine on August 31, 2010, when he was evaluated by Mesfin Seifu, M.D., a pulmonary specialist at the Central Ohio Pulmonary Disease and Sleep Medicine practice in Westerville, Ohio. Id. at 78, 82. He was referred to Dr. Seifu by his family doctor, Byron Blake M.D., secondary to complaints of persistent shortness of breath while walking short distances or climbing stairs. Pet. Ex. 13C, p. 8. Dr. Seifu performed multiple pulmonary function tests and diagnosed mild to moderate obstructive lung disease. Pet. Ex. 13C, p. 10. Dr. Seifu wrote to Dr. Blake with this diagnosis and also reported that he gave the petitioner “a pneumococcal vaccine today in the office.” Id.

Mrs. Keaton testified that she did not go to the doctor's appointment with her husband on August 31, 2010, but did ask him how it went as soon as he got home. Tr. at 13. She testified that he told her that he got a pneumonia shot and a flu shot. Id. She testified on cross examination that she remembered what her husband said about the shots because her husband was shocked that he was given these shots. Id. at 21-22. Apparently, he had not had a flu shot since 1976. Id. at 61.

Mr. Keaton testified that he was evaluated by Dr. Seifu, who performed several pulmonary tests. Tr. at 73-74; see also Pet. Ex. 13C, p. 10. At the end of the appointment, Dr. Seifu told him that he should go out into the waiting room and that he would be given several prescriptions, including one for an inhaler. Id. at 74-75. Mr. Keaton told the receptionist that he was waiting for prescriptions of which she was not aware. Id. at 81. Then a nurse came out and told him that the doctor wanted him to have flu and pneumonia vaccines. Id. He testified that she took him back into a small room and handed him one consent form for both vaccines, which he was reading when she came back and gave him the shots. Id. He did not finish reading or signing the paper at that time and left after he received the shots without completing the form. Id.; see also Pet. Ex. 1. He did remember that he received two shots in the left arm. Tr. at 81-83. He then walked out and forgot to get his prescriptions at the front desk. Id. at 81-84. He also recalled, that when he got home, he told his wife that they had given him flu and pneumonia shots. Id. at 80.

Mr. Keaton further testified that he began to feel some numbness around his face and lips that would come and go, beginning about a week later. Tr. at 62. In his affidavit Mr. Keaton described numbness and tingling developing in his fingers, arms and legs, and eventually difficulty controlling his bladder over the succeeding weeks and months. Pet. Ex. 9, p. 2. He further described on December 12, 2010, when he awoke from sleep, he had no feeling from his waist to his toes. Id. He was taken by ambulance initially to the Emergency Department at Mount Carmel West Hospital and then transferred and admitted to Riverside Methodist Hospital. Id.; Pet. Ex. 4, pp. 1-5; Pet. Ex. 6, p. 24. With some intervening transfers to rehab hospitals and returns to Riverside, he remained in-patient for about six weeks with a diagnosis of a Miller Fisher variant of GBS or AIDP. Pet. Ex. 6, pp. 11-19, 24, 28, 35-42.

Mr. Keaton developed pneumonia and respiratory failure and was on a ventilator for a prolonged period of time during this hospitalization. Id., pp. 24, 36. He also was unconscious for an extended period during this hospitalization. Id., pp. 517-19. It was incidentally discovered that he had a moderate to large size aneurysm in the anterior cerebral artery, which eventually required surgical intervention, but which did not explain any of his symptoms. Id., pp. 28, 60, 401, 503.

During the course of his hospitalization, Mr. Keaton was followed by Dr. Ridwan Lin, M.D., a neurologist. According to Mrs. Keaton, who kept a diary of her husband's hospitalization, Petitioner's Exhibit 16, on December 20, 2010, while her husband was unconscious, Dr. Lin asked her if her husband had had a flu shot and she said yes. Pet. Ex. 16 at 3. The note in her diary for December 20, 2010, says, "Doc said all of this could be flu shot."

Id. Mrs. Keaton testified that she had never heard of Guillain-Barre before and that it shocked her that her husband's condition could be caused by a flu shot. Tr. at 33, 40.

After his discharge from the hospital, petitioner consulted counsel with regard to filing a claim in the Vaccine Program. Counsel's office advised that he would have to provide proof that he had received a flu vaccine. A series of communications transpired between the petitioner and the COPD office. Initially, Mr. Keaton called the office and asked if they could confirm that he had had a flu shot. Tr. at 66. He testified that "they looked and came back and said that on August 31, 2010" he had had a flu shot. Id. He believed that he spoke to the lady who answered the phone. Id. A second time he called and asked to speak to a nurse and asked her to get his file to confirm that he had received a flu shot. Id. She confirmed that he had a flu shot while looking at his chart. Id. He subsequently went to the practice, probably on or about July 15, 2011, and was given a copy of an "Influenza Vaccine Consent Form, 2009-2010 Flulaval" (hereinafter "vaccine consent form"). Id. at 67; Pet. Ex. 12. Above the title was the name and address of Central Ohio Pulmonary Disease and Sleep Medicine Inc. Pet. Ex. 12. The name Ronald Keaton was written on the form, the pre-printed vaccine lot number for the Flulaval vaccine was crossed out and replaced with another lot number (AFLLA 284AA). The date 8/31/2010 appeared on the form and a fax number indicating that the form had been faxed on 8/31/2010 also appeared on the bottom of the document. Id. (It was later explained, in interrogatory answers, that it is likely that the COPD office in question was out of vaccine consent forms and one was faxed to the COPD office from their other office on that day). Mrs. Keaton faxed this form to their attorney on July 15, 2011, from her place of employment at Krogers, which fax number and name appears on the form. Tr. at 67.

Finally, Mr. Keaton went to the COPD office on January 8, 2013, and explained that he was having a problem with his medical record and needed to talk with someone and get some clarification. Tr. at 99. The subsequently filed interrogatories established that he met with Sheri Whalen, the Practice Administrator, and with Kerri Doss, the Billing Supervisor. Interrog. 28. He explained that the office personnel kept telling him that he had a flu shot but that the records did not confirm it. Id. Ms. Whalen consulted the chart and added a handwritten addendum saying, "1/18/13. Review of records shows both flu and pneumococcal vaccines were given. Only the pneumococcal was originally billed. We have corrected our error. Sheri Whalen, Administrator." Id.; Pet. Ex. 13C, p. 8; Pet. Ex. 10.

Mr. Keaton also testified that during the meeting, he sought to allay any fears that Ms. Whalen might have had regarding his intention to sue the practice. Tr. at 68-69; see also Pet. Ex. 12. To do so, he testified that he took a copy of the original vaccine consent form, filled it out and signed it with the original date of August 31, 2010. Tr. at 68-70; Pet. Ex. 12. The bottom of the form read, "Consent reviewed and injection(s) given by CR M.A." Pet. Ex. 12. "CR" appeared in handwriting on this copy of the form; it had not appeared on the prior copy. See Pet. Ex. 1. According to the interrogatory answers, "CR" is likely to have been the initials of Candace Roberts, a medical assistant, who could have given the injection and who was now deceased. Interrog. 2(b).

Mr. Keaton, after reviewing the Addendum to his chart added by Ms. Whalen, wanted more proof, so she directed the billing person to send an invoice for the August 31, 2010 flu shot

to his insurance company, knowing that it would be rejected as untimely. Interrog. 28. This form, Petitioner's Exhibit 11, was sent on January 8, 2013, and Mr. Keaton was given a copy. Tr. at 122-23; Pet. Ex. 11. All of the above referenced documentation was filed with the court as Petitioner's Exhibits 10, 11, and 12.

Notwithstanding this additional documentation, counsel for respondent filed a status report on January 14, 2013, noting that the original billing records did not include a charge for a flu shot and stating:

Respondent does not believe that these recently filed exhibits provide preponderant evidence that petitioner received a flu vaccination on August 31, 2010. First, the records from petitioner's insurance company do not state that any of the services billed by the PCP [pulmonary care physician] on August 31, 2010 relate to administration of a flu vaccination. Next, while petitioner produced a January 8, 2013 note from the "administrator" at the PCP's office that indicates petitioner received a flu vaccine on August 31, 2010, the note failed to explain what records the administrator reviewed/relied on for her assertion. Respondent has contacted petitioner's counsel and he has agreed to contact petitioner's PCP to determine what records were relied upon by the "Administrator" when drafting the January 8, 2013 note.

Respondent's Status Report, filed Jan. 14, 2013 at 2.

The case then proceeded to hearing on June 20, 2013 as described above. Mr. and Mrs. Keaton testified as described above. Subsequent to the hearing, the parties discussed with Special Master Zane a set of third party interrogatories to be agreed upon and sent to the COPD practice to address *inter alia* the questions raised in the respondent's status report. See Non-PDF Order, filed June 25, 2013; Order, filed July 16, 2013, at 1.

Sheri Whalen, the practice administrator, provided full and complete, verified answers to the interrogatories, which were filed by Special Master Zane on August 30, 2013. See Order: Filing Responses from Third Party in Record, Appendix B, Interrogatory Answers 1-39. In her answers, Ms. Whalen clarified multiple issues that had remained outstanding after the June hearing was held. These included:

- Dr. Seifu and Staci Hall, a medical assistant, who Ms. Whalen believed administered a vaccine that day, were no longer with the practice. Interrog. 1(a, c).
- Candace Roberts, to whom the initials CR on the vaccine consent form likely refer, was also a medical assistant. Interrog. 1(d). She may have been involved in administering vaccines or in answering Mr. Keaton's phone inquiries. Interrog. 2(b). Unfortunately, she died in June of 2012 and could not be asked about her role for these answers. Id.; Interrog. 3(b).
- The procedure for the administration of a vaccine at the COPD practice began with an order from the physician examining the patient. Interrog. 5. The medical assistant would then go to the lab where the syringes and vaccines are stored, note the vaccine in the

vaccine log, take a vaccine consent form to the patient, obtain the patient's consent, and administer the vaccine. Id. After the administration, the medical assistant would fill out a billing ticket to be given to the receptionist at the desk, who would then forward it to the billing office for generation of a bill for services rendered. Id.

- The COPD office attached 11 exhibits to its interrogatory answers. See Order: Filing Responses from Third Party in Record, Appendix B, Interrogatory Answers, attached COPD Exhibits 1-11, filed Aug. 30, 2013 [hereinafter "COPD Ex(s)."]. COPD Exhibit 1 is a copy of the "billing ticket," dated August 31, 2010. COPD Ex. 1. The billing ticket is a check-off form that includes spaces for diagnoses, consults, procedures and injections. Id. In the "Injections" column, there is a space for "influenza" and "Pneumovax." Id. The pneumovax box is checked, but the influenza box is not. Id.; Interrog. 7.
- COPD Exhibit 2 is a billing statement, dated September 15, 2010, which lists what was billed to Mr. Keaton's insurance company. COPD Ex. 2. It includes a charge for the pneumococcal vaccine and the administration thereof, on August 31, 2010, but it does not include a charge for a flu vaccine. Id.
- Ms. Whalen answered that the vaccine consent form, herein referenced as Pet. Ex. 1, did not tell her anything about whether or not Mr. Keaton had received a flu vaccine on August 31, 2010. Interrogs. 9, 10. She stated that the presence of the form indicated to her that the medical assistant was likely getting ready to use it prior to the vaccination, but that there was no indication on the form as to whether either the flu vaccine or the pneumococcal vaccine were given. Id.
- Ms. Whalen described Mr. Keaton's January 8, 2013 visit to the practice, which was the only time that she actually met with him. Interrog. 28. She answered that Kelli Doss, the billing supervisor, first saw Mr. Keaton but immediately asked for her help because he was trying to obtain documentation of the flu vaccine. Id. She reviewed the chart, noted that there was a copy of a handwritten note from Mr. Keaton to his counsel's staff saying that he had received confirmation of the flu shot from COPD and that he had attached the form that the nurse gave him. Id.; Pet. Ex. 13C, p. 5. She noted that Mr. Keaton was very firm in his conviction that he had received both a pneumococcal and flu vaccine on August 31, 2010, that COPD had somehow failed to bill for the flu vaccine, and that this was causing problems for him in obtaining compensation for an adverse reaction. Interrog. 28. She stated that she simply accepted Mr. Keaton's recollection as being correct and assumed that the COPD records were wrong. Id. In light of her conversation with Mr. Keaton, Ms. Whalen added the handwritten "addendum" to Dr. Seifu's chart indicating that he had received both vaccines on August 31, 2010. Id. Pet. Ex. 13C, p. 5; Pet. Ex. 10.
- Ms. Whalen acknowledged that she had no personal knowledge or recollection of whether Mr. Keaton actually received the two vaccines on August 31, 2010. Interrog. 29.
- Ms. Whalen stated that, at the time she wrote the addendum, she had forgotten that the office Vaccine Log existed. Interrog. 28.
- Ms. Whalen stated that the Vaccine Log does not indicate that any flu vaccines were administered on August 31, 2010, and that the number for the pneumococcal vaccine administered on that date was either 13394 or 1339Y as recorded in the Vaccine Log. Interrogs. 13, 14.
- The "lot number" on the vaccine consent form, AFFLA262AA, which was crossed out, and 284AA, which was handwritten next to the cross out on the form, were lot numbers

for the flu vaccine, but both numbers indicated expired batches of vaccine which were administered in September and October 2009. Interrogs. 16, 17; Pet. Ex. 1.

- In response to a question about the meaning of what appears to be a fax transmission number at the bottom of the vaccine consent form – “8/31/2010 TUE 11:03 [TX/RX NO 8214] 001” – Ms. Whalen answered that it likely indicated that their office near Mt. Carmel West Hospital, the west office, was out of the form and that a form was faxed over from their office near St. Ann’s Hospital. Interrog. 11.
- She had no knowledge or explanation as to why the first lot number would have been crossed out on the form and replaced by the other. Interrog. 12.

Additionally, in the “Plan” section of Dr. Seifu’s August 31, 2010 chart entry, Dr. Seifu noted, “[w]e would give him a pneumococcal vaccine.” Pet. Ex. 13C, p. 9. The chart entry does not mention a flu vaccine. Id. In his August 31, 2010 letter to Dr. Byron Blake, Mr. Keaton’s primary care physician, Dr. Seifu noted, “[t]he patient was ... strongly advised to quit smoking and I also gave him pneumococcal vaccine today in the office. I will see him back in three months for a follow-up.” Pet. Ex. 13C, p. 10. There was no reference to a flu vaccine in this letter. Id.

IV. Discussion

The undersigned Special Master did not have the opportunity to observe the demeanor of Mr. and Mrs. Keaton at the hearing which was conducted in June 2013 before then Special Master Zane. Nevertheless, after reading the responses of the Keatons to extensive and able direct and cross examination, I have concluded that the Keatons testified forthrightly and honestly to the best of their recollection as to the events of August 31, 2010. There is little doubt in my mind that Mr. Keaton does believe that he received a flu vaccine and a pneumococcal vaccine on August 31, 2010. The presence in his chart of the incomplete influenza vaccine consent form, if anything, provides some modicum of support for that belief. Mrs. Keaton testified credibly that, when he returned from the doctor’s office on August 31, 2010, he told her that he had received a flu vaccine and a pneumonia vaccine. Tr. at 12-13. She also testified that, when asked by Dr. Lin in the hospital on December 20, 2010 whether her husband had received a flu shot, she replied that he had. Tr. at 22-23, 41. But she was not present when the shot or shots would have been administered and therefore does not have first-hand knowledge of the administration.

If there was no other evidence, the Keatons’ testimony together with the incomplete influenza vaccine consent form in his chart might carry the day. Pet. Ex. 1. However, there is documentary evidence that, while not directly contradictory of the claim of a flu vaccine, is certainly strongly suggestive that only the pneumococcal vaccine was administered. Initially, Dr. Seifu’s “Plan” note in the chart specifically said that his office would administer a pneumococcal vaccine. Pet. Ex. 13C, p. 9. It did not mention a flu vaccine. Id. Second, in his letter to Dr. Blake, the family doctor, he reported that he did give petitioner the pneumococcal vaccine. Pet. Ex. 13C, p. 10. He did not mention a flu vaccine. Id. Third, COPD’s billing statement had a check off place for both an influenza and pneumococcal injection, one directly above the other. COPD Ex. 1 at 1. In Mr. Keaton’s chart the pneumococcal vaccine was checked and the flu vaccination was not. Id. Fourth, the billing was sent for the pneumococcal vaccine,

but not for the flu vaccine. COPD Ex. 2 at 1. Finally, Ms. Whalen answered that the vaccine log showed an entry for August 31, 2010, for the pneumococcal vaccine but not for the flu vaccine. Interrog. 13.

Thus, the evidence does not present a simple situation of a direct memory by the petitioner juxtaposed against a complete absence of record keeping by the practice. On the contrary, the record shows multiple references to the administration of the pneumococcal vaccine and none for the flu. While an oversight on the billing statement could plausibly have triggered the absence of a bill to the insurance company, it is unlikely that in addition both Dr. Seifu's chart and his letter to the family doctor would have included a reference to one vaccine and not the other if both had been ordered and administered. Finally, Ms. Whalen's interrogatory answers indicated that the vaccine log, which is the office-wide record for all vaccines given by date, did in fact show an administration of the pneumococcal but not the flu vaccine on the date in question. As such, contrary to the petitioner's recollection, the medical records strongly suggest that no flu vaccine was given.

The petitioner must prove by a preponderance of the evidence that he did receive a covered vaccine in order to be eligible for compensation in the program. On the basis of the above evidence, I have concluded that he has failed to carry that burden as to the flu vaccine. As the Program does not cover the pneumococcal vaccine for adults, this petition is dismissed. The clerk shall enter a judgment of dismissal.

IT IS SO ORDERED.

s/Thomas L. Gowen
Thomas L. Gowen
Special Master